



510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Maestro™ Total Wrist

Common Name: Total Wrist Joint

Classification Name: Wrist joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3800)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Biax™ A.F. Wrist System (DePuy Orthopedics, Inc.) – K031203

Universal2® Total Wrist System (Kineitkos medical) – K020554 & K030037

Device Description: The Maestro™ Total Wrist System consists of a two piece radial component with a molded bearing and a three-piece carpal component. The radial component is composed of a distal body with a modular stem. The distal bodies come in three sizes and have a molded polyethylene bearing surface. The stem is modular, assembled in the operating room by a screw assembly. The carpal component consists of 3 sub-components – a carpal head, a carpal plate and a capitate stem. The carpal head comes in 3 heights, standard, +2 and +4. This allows the surgeon to adjust for soft tissue laxity. Two lengths of carpal plates give the surgeon options of screw placement. Like the radial stems, a screw assembly attaches the capitate stems to the plate and head.

Intended Use: The Maestro™ Total Wrist System is indicated for use as a replacement of wrist joints disabled by pain, deformity and/or limited motion caused by:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Revision where other devices or treatments have failed
- 4) Scapholunate Advanced Collapse (SLAC) and other functional deformities
- 5) Trauma, including fractures of the distal radius and/or carpal bones

The device is intended to be implanted with bone cement.

MAILING ADDRESS

P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS

56 E. Bell Drive
Warsaw, IN 46581

OFFICE

574.267.6639

FAX

574.267.8137

E-MAIL

biomet@biomet.com

Summary of Technologies: The overall design, materials, surface finishes and processing of the Maestro™ Total Wrist are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: None provided

*All trademarks are owned by Biomet, Inc .except for the following:
Biax is a trademarks of DePuy Orthopaedics, Incorporated
Universal2 is a trademark of Kinetikos Medical Incorporated.*



OCT 7 - 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Manufacturing Corporation
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K042032
Trade/Device Name: Maestro™ Total Wrist System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWJ
Dated: July 27, 2004
Received: July 28, 2004

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

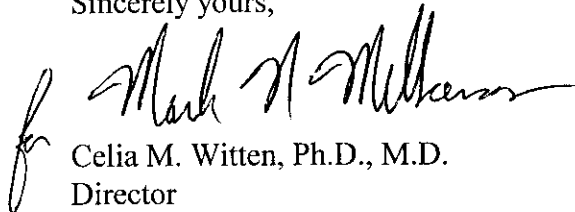
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042032

Device Name: Maestro™ Total Wrist System

Indications For Use: The Maestro™ Total Wrist System is indicated for use as a replacement of wrist joints disabled by pain, deformity and/or limited motion caused by:

- 1) Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis
- 2) Rheumatoid arthritis
- 3) Revision where other devices or treatments have failed
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The device is intended to be implanted with bone cement.

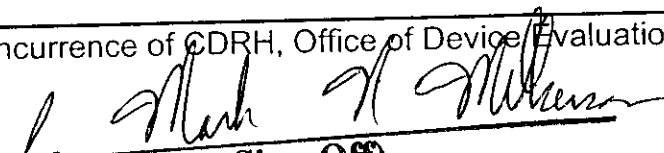
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K042032

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